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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,678	06/10/2005	Pierre Roy	079777-0574 (EGS-006 US)	3647
48329	7590	02/05/2008	EXAMINER	
FOLEY & LARDNER LLP 111 HUNTINGTON AVENUE 26TH FLOOR BOSTON, MA 02199-7610			HELM, CARALYNNE E	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,678	Applicant(s) ROY ET AL.	
	Examiner CARALYNNE HELM	Art Unit 4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1 page</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "communication" in claims 6 and 7 is used by the claim to mean something like "contact". While in a sense communication does indicate contact between multiple parties, in the context of the claims the use of the term does not provide adequate description such that one of ordinary skill in the art would understand the subject matter being claimed. Furthermore, term is indefinite because the specification does not clearly redefine the term.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Drizen et al. (U.S. PG Pub No. 2002/0037319).

Drizen et al. teach a device for the delivery of an active across the skin (see paragraph 1; instant claim 1). The device is taught to be composed of a backing sheet (first outer layer), polymer matrix (second inner layer) with hyaluronic acid (active principle), and an adhesive oriented such that the backing is coated with adhesive (e.g. adhesives of the sort use on bandages – skin adhesive) and the polymer matrix spans from one side to the other of the backing sheet (see figure 1, paragraph 226 lines 3-7, paragraph 227 lines 1-4, paragraph 228; instant claims 1-4). In addition, Drizen et al. teach that the polymer matrix is centered from end-to-end on the backing sheet allowing the adhesive to be exposed on either side (see figure 1 and paragraph 227 lines 3-4; instant claim 3). Drizen et al. teach that the backing sheet is composed of material that is impervious to oil or water (non-leaking), such as plastic (see paragraph 36 lines 1-3; instant claim 1). Drizen et al. also teach an embodiment with a backing sheet (first outer layer), permeable membrane (second inner layer) overlaying a reservoir with the active containing polymer, that is affixed to the backing sheet (see figure 6, paragraph 233, 234, and 236; instant claim 6). This embodiment also contains adhesive overlays on either side of the permeable membrane (see figure 6 and paragraph 233 lines 2-3; instant claim 6). In addition, Drizen et al. also teach the presence of a peel disk (protective seal) which protects against the release of active from the reservoir prior to use (see paragraph 235; instant claim 7). The intended use of “for ocular delivery” does not impart any structural limitation to the device, therefore it is not given patentable weight. Further, the device taught by Drizen et al. is capable

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of coming into contact with the eye. Thus instant claims 1-4 and 6-7 are anticipated by Drizen et al.

Claims 1, 4, 6, and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Miller et al. (U.S. PGPub No. 2004/0071761).

Miller et al. teach a device for non-invasive ocular drug deliver (see title and paragraph 2; instant claim 1). The device is taught to comprise a rigid or semi-rigid housing (first outer layer) with a reservoir or fluid retaining member that holds the pharmaceutical (active principle) compound and a rate limiting membrane (second inner layer) (see paragraph 74, paragraph 75 lines 12-16, and paragraph 76 lines 1-4; instant claims 1, 4, 6, and 8). In addition the housing also includes a seal that forms a tight seal against the eye of a patient (essentially non-leaking) (see 75 lines 3-6; instant claim 1). Thus claims 1, 4, 6, and 8 are anticipated by Miller et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drizen et al.

Drizen et al. teach a device for the delivery of an active across the skin (see paragraph 1; instant claim 1). Drizen et al. teach the device to have a backing sheet (first outer layer), permeable membrane (second inner layer) overlaying a reservoir that is affixed to the backing sheet (see figure 6, paragraph 233, 234, and 236; instant claim 1-2, and 4). This embodiment also contains adhesive overlays on either side of the permeable membrane (see figure 6 and paragraph 233 lines 2-3; instant claim 3). Further, this permeable membrane is taught to contain apertures (orifices) (see paragraph 236; instant claim 5). Since this layer has many apertures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have one of these pores located at the center of the device, as their location controls the delivery of the active in the polymer it covers (see paragraph 236; instant claim 5). Therefore claims 1-5 are obvious over Drizen et al.

Claims 1, 4, 6, and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. in view of Leonardi (U.S. Patent No. 4,727,869).

As discussed above Miller et al. anticipate claims 1, 4, 6, and 8, teaching an ocular drug delivery device with a rigid or semi-rigid housing, pharmaceutical containing reservoir and rate limiting membrane (see ***Claim Rejections - 35 USC § 102*** form claims 1, 4, 6, and 8). Miller et al. do not discuss a means to secure or apply the taught device. Leonardi teaches a device that immobilizes the eyelid where a splint is supplied with straps that encircle the head (see column 1 lines 43-45; instant claim 9). It would have been obvious to one of ordinary skill in the art at

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the time the invention was made to add the strap mechanism to the invention of Miller et al. in order to allow for the securing and easy removal of the device (see column 2 lines 10--14 and 26-29; instant claim 9). Therefore claims 1, 4, 6, and 8-9 are obvious over Miller et al. in view of Leonardi.

Conclusion

No claim is allowed.

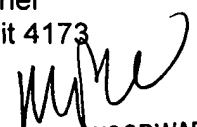
Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CH

Caralynne Helm
Examiner
Art Unit 4173



MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600